Remarks

A. Status of the Claims

Claims 1, 4, 8-10, 13-15, 17-19, 23-28, 39-42, 44, 46, and 48-51 were pending at the time of the Action. New claims 63-65 are added, non-limiting support for which can be found in the original claims and in the specification (*e.g.*, page 9, lines 10-19; page 10, lines 7-9; page 12, lines 18-19, 24, and 31; page 13, line 32, to page 14, line 14).

Thus, claims 1, 4, 8-10, 13-15, 17-19, 23-28, 39-42, 44, 46, 48-51, and 63-65 are pending.

B. Rejections Under 35 U.S.C. § 112, 1st Paragraph

The Action rejects claims 1, 4, 8-10, 13-15, 17-19, 23-28, 39-42, 44, 46, and 48-51 as allegedly lacking written description. The Action takes the position that the amendments to claim 1 are not supported because "neither the specification as filed, nor the original claims provide support for this combination" of limitations in claim 1. Action at 3. Applicant respectfully disagrees. The originally filed claims demonstrate that at the time of filing, Applicant had possession of the invention provided in claim 1.

Originally filed claims are part of the patent specification and provide written description support for later amendments that encompass the originally claimed subject matter. *See* § 2163 ("The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter.") (citing *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985)). Here, originally filed claim 20 provides written description support for all limitations of claim 1.

Claim 1 recites: "A wound healing composition comprising living human dermal fibroblast cells suspended within a single layered sterile, non-pyrogenic, solid or semi-solid, support matrix, said support matrix comprising a protein concentration of 3 to 12 $mg.ml^{-1}$ and a cell density of said human dermal fibroblasts of 450 to 2500 cells per mm^2, said composition having been incubated for 16 to 24 h at about 37°C." Originally filed claim 20 describes that precise combination of limitations.

Original claim 20 recites "[t]he would healing composition ***according to any preceding claim***, comprising about 450 to 2500 cells per mm^2 . . . ." *See* originally filed claim 20 (emphasis added). Thus, by its express terms, the additional limitation of claim 20 can be combined with the limitations of any of claims 1-19. Moreover, the originally filed claims that describe the relevant limitations in claim 1 (originally filed claims 1, 2, 3, 12, 16, and 17) make clear that claim 20 expressly encompasses a combination that includes all limitations of claim 1.

Specifically, originally filed claim 20 (which states that the wound-healing composition may comprise about 450 to 2500 cells per mm^2) depends from originally filed claim 16. Originally filed claim 16 states that the matrix can be non-pyrogenic and sterile. Claim 16 depends from originally filed claim 12, which states that the matrix is protein-based and may have a protein concentration of about 3 to 12 mg/ml. Originally filed claim 12 depends from originally filed claims 6 and 7, which state that the cells used in the composition may be fibroblasts, such as human dermal fibroblasts. Originally filed claims 6 and 7 are dependent on originally filed claim 3, which states that the composition can be incubated at 37°C. Originally filed claim 3 depends from originally filed claim 2, which states that the composition can be incubated for 16 to 24 h. Finally, originally filed claim 2 depends from originally filed claim 1, which states that the wound healing composition can be a single-layered composition comprising

living cells within a support matrix. Thus, the originally filed claims make clear that Applicant had possession of a composition comprising all elements of claim 1.

The Action specifically asserts that "[t]he only support in the specification as filed for 'human dermal fibroblasts within a sterile, non-pyrogenic support matrix' is in reference to a support matrix formed by a thrombin-mediated polymerization of fibrinogen." Action at 3. However, as explained above, the combination of human dermal fibroblasts with a sterile, non-pyrogenic support matrix was specifically described by the originally filed claims. The Action also takes the position that Applicant has improperly combined claim limitations. But Applicant respectfully submits that there is nothing improper about combining the elements of a dependent claim with the elements of claims from which it depends. *See* MPEP § 608.01(n).

For these reasons, Applicant respectfully submits that the rejections are overcome.

C. Rejections Under 35 U.S.C. § 103

The Action rejects claims 1, 4, 8-10, 13-15, 17-19, 23-28, 39-42, 44, 46, and 48-51 as allegedly obvious over WO 2002/072113 ("Leek") in view of U.S. Publication 2004/0031067 ("Herlyn"), U.S. Patent 7,196,054 ("Drohan"), and U.S. Publication 2002/0018757 ("Harichian"). Applicant respectfully disagrees.

1. The obviousness rejections are overcome.

The obviousness rejections are overcome because they fail to address all limitations of the claims. "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03 (quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)). Even if the Action was correct that certain limitations in claim 1 are not supported by the original specification, those limitations must nonetheless be considered and given weight when evaluating whether the claims meet the nonobviousness requirement. *Id.*

("When evaluating claims for obviousness under 35 U.S.C. 103, all the limitations of the claims must be considered and given weight, including limitations which do not find support in the specification as originally filed (i.e., new matter).") (citing *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff'd* 738 F.2d 453 (Fed. Cir. 1984)).

The Action does not discuss, and thus does not appear to consider, several limitations of claim 1. For example, although the action discusses the single-layered limitation in the context of the Leek and Herlyn references, it does not mention several other components of claim 1, such as the non-pyrogenic limitation, the recited protein concentration, the recited cell density, or the recited incubation conditions.

Indeed, it appears that the cited references do not disclose the limitations of the claims. For example, the primary reference relied upon by the Action, Leek, fails to disclose or suggest the sterile, non-pyrogenic, protein concentration, cell density, and incubation period and temperature limitations of claim 1. Further, the secondary references (Herlyn, Drohan, and Harichian) fail to supplement Leek's deficiencies. For example, no cited reference teaches or suggests the use of a non-pyrogenic support matrix or a composition that has "been incubated for 16 to 24 h at about 37°C." Applicant requests that the Examiner properly give weight to all recited claim limitations. *See* MPEP § 2143.

Applicant's composition having been incubated for 16 to 24 hours at about 37°C enjoys structural differences when compared with the cited compositions. Applicant's specification at page 9, line 29, to page 10, line 5, and corresponding data confirm:

> The present inventors have found that under normal culture conditions, for example, a liquid culture of human dermal fibroblasts incubated in a standard culture medium at 37°C, development of a wound-healing phenotype may typically take 2 to 3 days. However, incubation of such fibroblasts in a suitable environment such as in a support matrix and/or a wound shortens the development

> process, so that before 24 hours the cells may have entered or reached the wound-healing phenotype. Thus, incubation of cells in a suitable support matrix and/or wound results in a shorter development time to reach a wound healing phenotype than standard (for example, liquid) culture conditions.

The specification also explains that this shorter development time to produce a wound-healing phenotype was surprising in that it results in a composition that is in an optimal stage "for accelerating or assisting wound healing" (page 8, lines 21-30) which includes the cells being "optimally suited for secretion of extraceullular matrix with minimal inappropriate fibrinnolysis" (page 10, line 31, to page 11, line 1).

Given that the combination of Leek with Herlyn, Drohan, and Harichian fails to disclose or suggest all limitations in Applicant's claimed composition, it is respectfully submitted that the current obviousness rejection cannot be maintained.

For at least the reasons stated above, Applicant requests that the current obviousness rejection be withdrawn.

2. *New claims 63-65 are nonobvious for additional reasons.*

In addition to the reasons provided above, new claims 63-65 are nonobvious for other reasons as well.

First, to the extent that the Action's position is based on the "comprising" language of claim 1, see Action at 4-5, claim 63 is directed to the composition of claim 1, wherein the composition ***consists of*** living human dermal fibroblast cells suspended within a single-layered sterile, non-pyrogenic, solid or semi-solid, support matrix.

Second, to the extent that the rejections rely on prior art that teaches or suggests a multi-layer composition comprising more than one cellular layer (e.g., Herlyn), claim 64 is directed to the composition of claim 1, wherein the composition comprises no additional cellular layers.

Third, claim 65 is directed to the wound healing composition of claim 1, wherein the composition comprises stacked layers comprising substantially uniform single layers. The cited references do not appear to teach or suggest that limitation.

Thus, Applicant respectfully submits that claims 63-65 are nonobvious.

D. Conclusion

Applicant requests that this case proceed to allowance. Should there be any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicant's representative at (512) 536-3020.

Respectfully submitted,

for Michael R. Krawzsenek
Reg. No. 51,898
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 536-3020
(512) 536-4598 (facsimile)

Date: August 11, 2011